

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>  <hr/> <b>THIS DOCUMENT RELATES TO:</b>  <b>WAVE 3 CASES LISTED IN EXHIBIT A</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
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**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT'S  
MOTION TO EXCLUDE GENERAL-CAUSATION TESTIMONY OF NEERAJ KOHLI,  
M.D., M.B.A.**

**Prior History of Kohli Daubert Motions**

Plaintiffs have previously filed their Memorandum In Opposition To Defendants' Motion to Exclude General Causation Testimony of Dr. Neeraj Kohli, M.D., M.B.A., relating to Wave 1 Cases, as Document 2178, on 5/09/2016. As to Wave 2, Plaintiff filed their Notice of Adoption of Prior *Daubert* Response as MDL Document 2510. This Honorable Court issued its *Daubert* Ruling in Wave 1 on September 1, 2016, filed as Document 2709. Because the six objections raised by Defendant in this current Motion to Exclude for Dr. Kohli's Wave 3 opinions closely track, and in fact, raise the same objections as have been addressed in Waves 1 and 2, Plaintiffs hereby incorporate Documents 2178 and 2510 into this opposition and rely upon the arguments expressed therein as are supplemented by this filing. Plaintiffs attach Document 2178 and 2510 as exhibits B and C.

Plaintiffs are cognizant of this Court's admonition that "the parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert's* core considerations for assessing expert testimony."

## **EXECUTIVE SUMMARY**

1. TVT-O is a defective design for a multitude of reasons, including the physical design of the components, particularly the trocars; the angles and blind passages required, and the inadequacy of instructions. To suggest surgical procedure is all that Dr. Kohli complained of is disingenuous.
2. TVT-O has demonstrably higher rates of groin pain and complications that are not within reasonable parameters, and are not properly disclosed to the patient or the implanting physician. The words “unacceptably high” seem accurate and descriptive.
3. As to Dr. Kohli’s views of unperformed pre marketing clinical testing, Plaintiffs will follow their positions taken in Waves 1 and 2 and not offer expert opinions on hypothetical clinical testing.
4. Dr. Kohli’s opinions that TVT-O is not appropriate for certain obese or active women is well supported by literature and his clinical experience and are helpful to the jury’s understanding of the inadequacy of the instructions offered by the Defendant.
5. Dr. Kohli’s opinions relating to the difficulty in using the designed tools provided by Defendant are relevant and helpful to the jury in demonstrating design defect, and his discussion of the difficulties encountered by physicians is not an opinion relating to competence.
6. Dr. Kohli will not offer opinions as to Ethicon’s intent, motives, or state of mind. Having had direct contact with Ethicon specifically relating to training and use of the TVT and TVT-O approach in the relevant time period, he is well qualified to provide helpful insights into the knowledge of implanting doctors, and to contrast that with factual information known within Ethicon at the same time.

## **DISCUSSION**

All that is required is that the expert be qualified; that the opinions be “based upon sufficient facts or data,” and is the “product of reliable principles and methods,” which have been reliably applied to the “facts of the case.” *Tyree et. al v. Boston Scientific*, 2014 WL 5320566 at\*2; *In re Bard, Inc.*, 948 F.Supp2d 589, 601 (SDWVA 2013).

Despite this clear imprimatur that the Court's ruling on receipt of expert testimony is as gatekeeper to make "preliminary assessment" of whether the proffered testimony is helpful and reliable, Defendant insists on creating a gauntlet of absolutism and intricate deconstruction that is unwarranted and finds no support in the text of *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 589 (1993).

This Court has recognized that many issues complained of by Defendant in filing its tedious and lengthy *Daubert* motions on every single Plaintiff's expert are not properly *Daubert* motions, but are best left to the trial court who will have context and primacy for regulating the scope of expert opinion to be heard by the jury. In this regard, Dr. Kohli is certainly highly qualified by education and by experience; he has actual clinical experience in implanting MUS, including TVT and TVT-O; he has actually had direct dealings with Defendant on design and safety issues; and he has reviewed the pertinent literature to insure that his opinions are based upon well founded science and medicine. All that is required for the Court to decide at this preliminary juncture is that the witness is qualified and the opinions are based upon well founded scientific principle.

### **I. Dr. Kohli's Design Defect Opinions Are Relevant.**

Plaintiffs incorporate herein their arguments as to Opinion 1 by reference (Exhibit B at p. 4), and understand and respect this Honorable Court's ruling of September 1, deferring consideration of this opinion.

### **II. Dr. Kohli's Opinions Concerning Complications Are Relevant And Reliable.**

As supplement to their arguments incorporated herein by reference (Exhibit B at pg. 7), these Plaintiffs point out that as Heraclitus states, the river flows. And as time passes, the medical literature and clinical experience become ever more clear as to the risk involved in the TVT-O blind transobturator needle approach. Studies show that incidence of groin pain are close

to double for the transobturator approach.<sup>1</sup> Clinicians decline to use the TVT-O because of the higher rates of pain associated with the device.<sup>2</sup> The passage of time makes it clear that alternative techniques offer advantages without the risks of the blind passage approach. Plaintiffs pray reference to additional materials supplied and referenced in Footnote 2 and included in the exhibits as additional objective evidence of higher, unacceptable complications presented by TVT-O. These materials are offered to show that the opinions of Dr. Kohli are not ipse dixit as argued by the Defendant, but are reflective of main stream understanding of the

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<sup>1</sup> See, e.g., *Evaluation and Management of Mid-urethral Sling Complications*, Brown, Cohn, Kaufman, Dmochowski; Reynolds, Curr. Bladder Dysfunct. Rep., d0110.1007/s11884-016-0365-4, Apr 18, 2016:..."the TOT approach resulted in more neuromuscular complaints such as leg weakness, pain and groin numbness when compared to RP MUS: 9.7% versus 5.4% respectively" This paper is reprinted as Exhibit D in the appendix and is very instructive because it reports on TOMUS trial which was an RCT and finds that the retrospective studies show complication rates much higher than those previously reported in RCTs, suggesting that RCTs underestimate the degree of complication. Further included are recent studies that demonstrate degradation of mesh within the body, showing continual inflammatory process, and further evidence that the mythology that MUS slings do not degrade and that they are safe can be put to rest. At a minimum, the recent science is showing additional support for Dr. Kohli's views of defect. See e.g. *Characterization of the host inflammatory response following implantation of prolapse mesh in rhesus macaque*, Brown, Mani, Nolfi, Liang, Abrmowitch, and Moelli, AJOG, accepted for publication August 2, 2015; reprinted as Exhibit E *Degradation of polypropylene in vivo: Amicroscopic analysis of meshes explanted* from patients; Iakovlev, Guelcher, Bendavid, J. Biomed Mater Res Part B 2015: 00B:000-000 accepted 30 July, 2015 (Exhibit F).

<sup>2</sup>Dr. Lowman, Ethicon expert and Head of Urogynecologic Services, Kaiser Permanente Georgia, said at her deposition:

Q: Doctor, in your report you indicated that you have placed approximately 800 TVT and TVT-O devices. Is that correct? I'm at page 2.

A: Yes.

Q: And do you use both TVT and TVT-O?

A: No.

Q: What do you use --

A: The TVT.

Q: -- currently? Did you ever use TVT-O?

A: I have used it before, yes.

Q: And is there a reason why you exclusively use TVT today?

THE WITNESS: Yes. The retropubic route has a lower risk of pelvic pain and groin pain and has a higher success rate --

Q: I see.

A: than obturator slings.

Q: And was there a date that you can point to that that was the date that you felt that the evidence that you have just recited was sufficient for you to not use TVT-O: anymore?

THE WITNESS: No.

...

Q: I see. So while you were either in residency or fellowship, you made that determination?

A: That's correct.

Deposition of Dr. Lowman, pg. 23 line 9-pg.24 line18 (objections excluded for readability)  
(Excerpt included as Ex. G)

unacceptably high rates of complication. Ethicon has retained an expert who refuses to use TVT-O because of its higher rates of pelvic and groin pain. If it is the word “unacceptable” that offends, then Dr. Kohli will simply point out the 9.7% neuromuscular pain for TOT versus the 4.5% for RP and allow the jury to conclude on their own that double of the complication rate is an important factor in seeing the product as defective.

### **III. Dr. Kohli’s Will Not Opine on Hypothetical Clinical Testing**

As to opinion 3, while Plaintiffs will not seek an opinion from Dr. Kohli relating to hypothetical clinical trials, Plaintiffs will fully point out the inherent dissonance in Ethicon’s positions taken at differing points in this memorandum and in the litigation claiming that scientific studies which look at trans obturator MUS outcomes cannot be used to form opinions about the TVT-O because they are not limited to only a specific brand name by the investigators with the fact that Ethicon had full opportunity to conduct its scientific trials relating to safety and efficacy of the TVT-O and chose instead to rely on its experience with TVT in its marketing and promotional activities.

### **IV. Dr. Kohli’s Opinions on The Appropriateness of the TVT-O For Certain Patient Populations Are Reliable and Helpful**

As supplement to their arguments as to Opinion 4, incorporated herein by reference, Plaintiffs note that in its Order of September 1 relating to Dr. Kohli, the Court found Dr. Kohli’s showing deficient that various groups of patients suffered from higher rates of complication. Plaintiffs respectfully crave attention to Dr. Kohli’s Rule 26 Report at page 35, Footnotes 40 and 41, which make reference to Ethicon documents and to various published medical articles which address differing complications suffered by subgroups. Plaintiffs request the Court to find that Dr. Kohli’s opinion is based upon generalized facts that are consistent with the medical community at large and are not the product of an *ipse dixit* reasoning. Differing rates of complications for mesh MUS for various groups is known within the medical community and the

shorthand reference to this widely known fact as it applies to defective design and inadequate instruction.<sup>3</sup>

**V. Ethicon's attempt to recast Dr. Kohli's opinions on defective design as opinions regarding the competency of other physicians is unavailing.**

As supplement to their arguments as to opinion 5, incorporated herein by reference, Dr. Kohli's opinions regarding the difficulty of the blind inside out technique as evidence of design flaw are part and parcel of the general body of medical knowledge. For example, in a case entitled *Beard v. Ethicon* (Case No: 2:12-cv-02025), a Wave 2 case, the explanting physician Dr. Holley said of the TVTO:

Q. Did you personally, Doctor, ever spend time learning about and use the TVT-O?

A. We did. We preferred the retropubic sling for several reasons. Number one, because we had much more experience with that than with the transobturator. The other reason is there is compelling evidence in the literature for women who had a more severe type stress incontinence called intrinsic sphincter deficiency. The trials comparing the two types of slings showed that the -- when I say TVT, I just mean retropubic slings in general, never mind what kit -- but that the retropubic sling was more effective for women who had intrinsic sphincter deficiency than the transobturator.

...

A. We found the retropubic sling was easier to teach than the transobturator.

See Holley Dep. 42:12-43:14; 43:8-9, attached as Exhibit H.

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<sup>3</sup> E.g., Exhibit I, M. McLennan and C. Melick, "Bladder Perforation During Tension- Free Vaginal Tape Procedures: Analysis of Learning Curve and Risk Factors," *Obstet Gynecol* 2005; 106:1000-4, which shows that as of 2005, obesity was a factor in complication rates.

And certainly we quoted earlier from Dr. Lowman, their own expert, her decision not to use TVTO because of its complications. See Footnote 2. These opinions do not spring as *ipse dixit*. They are part of the general weight of medical knowledge and if the good doctor in the midst of an exhaustive and instructive Rule 26 report happened to have thinly referenced a point that he took as a given, then he is not shown to be unreliable, and the opinion is not springing forth as poor science. He should be given an opportunity to enunciate and to defend on cross examination these opinions in context.

**VI. Dr. Kohli's Opinions As To Ethicon's Knowledge Are Reliable And Helpful To The Jury.**

As to opinion 6, Plaintiffs' brief (Ex. B at p. 12-13) is incorporated herein by reference.

**CONCLUSION**

These Plaintiffs, understanding and respecting this Court's order of September 1, 2016, nonetheless respectfully request that this Court consider that several of Dr. Kohli's opinions as were stated in shorthand form in his exhaustive Rule 26 report were based upon legally adequate sources of factual information available to the medical community. The adequacy and admissibility of these opinions are better made on a contextual evidentiary record in the context of active trial proceeding.

Respectfully submitted,

Date: October 11, 2016

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 11, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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